Donald R. Warren, C.B. No. 138933 Warren • Benson Law Group 7825 Fay Ave., Suite 200 2 La Jolla, CA 92037 Telephone: (858) 456-1900 3 Facsimile: (858) 454-5878 4 donwarren@warrenbensonlaw.com 5 Attorneys for Qui Tam Plaintiff б 7 8 UNITED STATES DISTRICT COURT 9 CENTRAL DISTRICT OF CALIFORNIA 10 WESTERN DIVISION 11 -3443 GHK/FMC UNITED STATES, the STATES of CALIFORNIA, DÉLAWARE FLORIDA, HAWAII, ILLINOIS LOUISIANA, MASSÁCHUSETTS. 13 COMPLAINT FOR VIOLATIONS OF NEVADA, NEW HAMPSHIRE. FALSE CLAIMS ACTS 31 U.S.C. §3730, et seq; Cal. Govt. Code § 12650 TENNESSEE, TEXAS and 14 VIRGINIA, the LOUISIANA et seq; Del. Code Ann., Title 6, § 1201 et seq; Fla. Stat. 68.081 et seq; Haw. 15 MEDICAL ASSISTANCE Rev. Stat. § 661-22 et seq; 740 III. Comp. Stat. Ann. § 175/1 et seq; La. Rev. Stat. Ann. § 46:439.1 et seq; PROGRAMS and the DISTRICT 16 OF COLUMBIA, ex rel., Thomas Morrow, Mass. Ann. Laws Ch. 12, § 5(A)-(O) et seq; Nev. Rev. Stat. § 357.010 et seq; New Hampshire Rev. Stat. Ann., 17 **Plaintiffs** 18 167:61 et seq; Tenn. Code Ann. § 71-5-181 et seq; Tex. Hum. Res. Code § 36.001 et seq; Va. Code Ann. § 8.01-216.3 et seq; and D.C. Code Ann. § 1-19 PFIZER, INC., 20 Defendant 1188.13 et seg 21 22 JURY TRIAL DEMANDED JUN 1 3 2006 23 LODGED UNDER SEAL PURSUANT TO 31 U.S.C. §§ 24 3730(b)(2) and (3) COMES NOW QUI TAM RELATOR-PLAINTIFF Thomas Morrow. 25 suing for himself and for the United States of America, pursuant to 31 U.S.C. § 26

3730 et seg, the State of California pursuant to Cal. Govt. Code § 12650 et seg, the

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This action is based upon the defendant knowingly causing false claims to be submitted by healthcare providers to Medicaid and other federally funded programs, and the defendant knowingly causing to be used, false records or statements to get false or fraudulent claims paid or approved, by knowingly falsifying certification of compliance with the Stark Act, 42 U.S.C. § 1395nn, and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2. The defendant paid illegal kickbacks to participating physicians in the form of cash payments of between \$800 to \$1,000 per year for each patient whom the participating physicians treated with defendant's growth hormone drugs.

I. <u>JURISDICTION</u>

- Jurisdiction over the federal claims asserted herein is based upon 2. federal subject matter pursuant to 31 U.S.C. § 3729 et seq.
- Jurisdiction over the state claims asserted herein is based upon 31 3. U.S.C. § 3732(b) and supplemental jurisdiction pursuant to 28 U.S.C. § 1367.
 - 4. The Court may exercise personal jurisdiction over the defendant

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pursuant to 31 U.S.C. § 3732(a).

II. VENUE

5. Venue is proper in the Central District of California, under 31 U.S.C. § 3732 and 28 U.S.C. §§ 1391(b) and (c) because the defendant transacts business in this District and because the defendant committed acts within this district that violated 31 U.S.C. § 3729.

III. PARTIES

- 6. Qui tam plaintiff Thomas Morrow is a licensed physician whose work includes involvement with growth hormone pharmaceuticals. Dr. Morrow is a United States citizen and a resident of the State of Georgia, residing in Alpharetta, Georgia.
- 7. The United States of America, through its agencies, including, Centers for Medicare and Medicaid Services, and its Veterans Administration, among others, has provided funds for prescription pharmaceutical products, and related physician services, which were billed with false certifications of compliance with the Stark Law and the Anti-Kickback Statute.
- 8. Each of the States of California, Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, New Hampshire, Tennessee, Texas and Virginia, and the District of Columbia, through its respective participation in the Medicaid program, has provided funds for pharmaceutical products which were billed with false certifications of compliance with the Stark Law and Anti-Kickback Statute.
- 9. Pfizer, Inc. ("Pfizer"), is a for-profit Delaware corporation with its headquarters located in New York, New York. Pfizer is one of the largest

manufacturers of prescription drugs in the United States, and sells millions of dollars of its prescription pharmaceuticals to Federal, State and District of Columbia medicaid programs, and other Federal health care programs, annually.

IV. BACKGROUND

- 10. More prescription drugs are purchased through the Medicaid program than through any other insurance program in the United States. The Medicaid program is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. Under the Medicaid program, the Federal government provides matching funds and ensures that the states comply with minimum standards in the administration of the program.
- 11. As a result of its involvement in the Medicaid program, the federal government provides at least half of the funds used to purchase Medicaid reimbursable pharmaceuticals and related physician services. Not surprisingly, in order to prevent waste, fraud and abuse, the Medicaid program has explicit restrictions against compensation paid to physicians to induce the use of a manufacturer's products. Medicare providers have a legal duty to familiarize themselves with Medicare's reimbursement rules, including those stated in the Medicare Manuals. Heckler v. Community Health Services of Crawford County, Inc., 467 U.S. 51, 64-65 (1984). This duty also applies to Medicaid providers.
- 12. Growth Hormone Pharmaceuticals. Growth hormone (GH) is used to cause growth in children who are deficient in the hormone or who have short stature with normal growth hormone levels. GH is used for about 10 years in most children who start it for GH deficiency. There are also a number of other FDA

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approved indications for this drug where it is used for differing periods of time. Currently, there are about 25,000 patients receiving GH.

Many years ago, prior to the discovery of the ability to create GH 13. using recombinant technology, GH was of human brain origin. In the 1970's, several children developed a neurological disorder similar to mad cow disease and the human brain source hormone was removed from the market. Almost thirty years ago, in the late 1970's, Genentech developed the processes to create this hormone using recombinant technology. A registry was created to follow these children to ensure safety of this new technology.

PFIZER'S MISCONDUCT

- The registries have continued, but not to legitimately gather research 14. data as there is very little that needs to be studied with this hormone. The true reason the registries have continued, is to create a pretext to funnel kickbacks to prescribing physicians, to promote market share. A number of pharmaceutical companies pay physicians from \$800 to \$1,000 per patient, per year, to log information from the patient's chart into the company's on-line registry. This effort takes approximately 5 - 10 minutes, once every six months, to input/update the patient's weight, height, growth rate and dosage. The payments are way out of line with arms-length amounts, as the data is the same as the physicians are already gathering in each patient's chart. Further, many physicians allow pharmaceutical sales reps to use the physician's office to enter the data into the registry internet site so the physician can be paid the kickback.
- The pharmaceutical company Teva recently received FDA approval 15. for its GH product, TevTropin. Because Teva does not pay kickbacks, its product

has not sold well, despite the fact that TevTropin is approximately 40% less expensive than the competitors' GH products. In addition, all of these growth hormones are the same. They use human DNA to code for the same 186 amino acids. All of these products also have the same generic name.

- 16. Defendant's illegal payments in violation of the Anti-Kickback Statute and the Stark Law have caused false claims to be submitted by healthcare providers to Medicaid and other federally funded programs, and have caused healthcare providers to use false records or statements to get false or fraudulent claims paid or approved, by knowingly falsifying certification of compliance with the Stark Act, 42 U.S.C. § 1395nn, and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2). In turn, this conduct has also caused states to unknowingly submit false claims to the United States for the United States' share of these unreimbursable growth hormone claims under the Medicaid program.
- 17. These false claims regarding compliance with the Anti-Kickback Statute and the Stark Law have involved Pfizer kickbacks of approximately \$7 million over the past 10 years and have resulted in Medicaid program payments of more than one hundred million dollars.

VI. <u>COUNT ONE</u>

(For Violation of 31 U.S.C. § 3729 et seq.)

- 18. Qui tam plaintiff hereby realleges and incorporates herein by this reference paragraphs 1 through 17, inclusive, hereinabove, as though fully set forth at length.
- 19. Defendant has knowingly caused to be submitted, false claims for payment, as set forth above, in violation of 31 U.S.C. § 3729(a)(1). Additionally,

defendant has knowingly caused to be used false records or statements to get false or fraudulent claims paid by the United States, in violation of 31 U.S.C. § 3729(a)(2). As a result of such knowing submission of false claims, defendant has wrongfully caused payments to be made from, and has wrongfully received monies derived from, the United States Treasury in the millions of dollars.

VII. COUNT TWO

(For Violation of Cal. Govt. Code § 12650 et seq.)

- 20. Oui tam plaintiff hereby realleges and incorporates herein by this reference paragraphs 1 through 17, inclusive, hereinabove, as though fully set forth at length.
- 21. Defendant's knowing misconduct as described above is in violation of Cal. Govt. Code § 12650 et seq., and has caused damage to the State of California in an amount to be determined at trial.

VIII. COUNT THREE

(For Violation of Del. Code Ann., Title 6, § 1201 et seq.)

- 22. Qui tam plaintiff hereby realleges and incorporates herein by this reference paragraphs 1 through 17, inclusive, hereinabove, as though fully set forth at length.
- 23. Defendant's knowing misconduct as described above is in violation of Del. Code Ann., Title 6, § 1201 et seq, and has caused damage to the State of Delaware in an amount to be determined at trial.

IX. COUNT FOUR

(For Violation of Fla. Stat. 68.081 et seq.)

Qui tam plaintiff hereby realleges and incorporates herein by this 24.

reference paragraphs 1 through 17, inclusive, hereinabove, as though fully set forth at length.

25. Defendant's knowing misconduct as described above is in violation of Fla. Stat. 68.081 et seq, and has caused damage to the State of Florida in an amount to be determined at trial.

X. COUNT FIVE

(For Violation of Haw. Rev. Stat. § 661-22 et seq.)

- 26. Qui tam plaintiff hereby realleges and incorporates herein by this reference paragraphs 1 through 17, inclusive, hereinabove, as though fully set forth at length.
- 27. Defendant's knowing misconduct as described above is in violation of Haw. Rev. Stat. § 661-22 et seq, and has caused damage to the State of Hawaii in an amount to be determined at trial.

XI. COUNT SIX

(For Violation of 740 III. Comp. Stat. Ann. § 175/1 et seq.)

- 28. Qui tam plaintiff hereby realleges and incorporates herein by this reference paragraphs 1 through 17, inclusive, hereinabove, as though fully set forth at length.
- 29. Defendant's knowing misconduct as described above is in violation of 740 Ill. Comp. Stat. Ann. § 175/1 et seq, and has caused damage to the State of Illinois in an amount to be determined at trial.

XII. COUNT SEVEN

(For Violation of La. Rev. Stat. Ann. § 46:439.1 et seq.)

30. Oui tam plaintiff hereby realleges and incorporates herein by this

reference paragraphs 1 through 17, inclusive, hereinabove, as though fully set forth at length.

31. Defendant's knowing misconduct as described above is in violation of La. Rev. Stat. Ann. § 46:439.1 et seq, and has caused damage to the State of Louisiana and its Louisiana Medical Assistance Programs in an amount to be determined at trial.

XIII. COUNT EIGHT

(For Violation of Mass. Ann. Laws Ch. 12, § 5(A)-(O) et seq.)

- 32. Qui tam plaintiff hereby realleges and incorporates herein by this reference paragraphs 1 through 17, inclusive, hereinabove, as though fully set forth at length.
- 33. Defendant's knowing misconduct as described above is in violation of Mass. Ann. Laws Ch. 12, § 5(A)-(O) et seq, and has caused damage to the State of Massachusetts in an amount to be determined at trial.

XIV. COUNT NINE

(For Violation of Nev. Rev. Stat. § 357.010 et seq.)

- 34. Qui tam plaintiff hereby realleges and incorporates herein by this reference paragraphs 1 through 17, inclusive, hereinabove, as though fully set forth at length.
- 35. Defendant's knowing misconduct as described above is in violation of Nev. Rev. Stat. § 357.010 et seq, and has caused damage to the State of Nevada in an amount to be determined at trial.

XV. COUNT TEN

(For Violation of New Hamp. Rev. Stat. Ann. § 167:61, et seq.)

- 36. Qui tam plaintiff hereby realleges and incorporates herein by this reference paragraphs 1 through 17, inclusive, hereinabove, as though fully set forth at length.
- 37. Defendant's knowing misconduct as described above is in violation of New Hamp. Rev. Stat. Ann. § 167:61, et seq., and has caused damage to the State of New Hampshire in an amount to be determined at trial.

XVI. COUNT ELEVEN

(For Violation of Tenn. Code Ann. § 71-5-181 et seq.)

- 38. Qui tam plaintiff hereby realleges and incorporates herein by this reference paragraphs 1 through 17, inclusive, hereinabove, as though fully set forth at length.
- 39. Defendant's knowing misconduct as described above is in violation of Tenn. Code Ann. § 71-5-181 *et seq*, and has caused damage to the State of Tennessee in an amount to be determined at trial.

XVII. COUNT TWELVE

(For Violation of Tex. Hum. Res. Code § 36.001 et seq.

- 40. Qui tam plaintiff hereby realleges and incorporates herein by this reference paragraphs 1 through 17, inclusive, hereinabove, as though fully set forth at length.
- 41. Defendant's knowing misconduct as described above is in violation of Tex. Hum. Res. Code § 36.001 et seq, and has caused damage to the State of Texas in an amount to be determined at trial.

XVIII. COUNT THIRTEEN

(For Violation of Va. Code Ann. § 8.01-216.3 et seg.)

- 42. Qui tam plaintiff hereby realleges and incorporates herein by this reference paragraphs 1 through 17, inclusive, hereinabove, as though fully set forth at length.
- 43. Defendant's knowing misconduct as described above is in violation of Va. Code Ann. § 8.01-216.3 et seq, and has caused damage to the State of Virginia in an amount to be determined at trial.

IXX. COUNT FOURTEEN

(For Violation of D.C. Code Ann. § 1-1188.13 et seq.)

- 44. Qui tam plaintiff hereby realleges and incorporates herein by this reference paragraphs 1 through 17, inclusive, hereinabove, as though fully set forth at length.
- 45. Defendant's knowing misconduct as described above is in violation of D.C. Code Ann. § 1-1188.13 et seq, and has caused damage to the District of Columbia in an amount to be determined at trial.

WHEREFORE, qui tam plaintiff prays for relief as follows:

- 1. Full restitution to the United States, the States of California,
 Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, Tennessee,
 Texas, Virginia and the District of Columbia of all money damages sustained by
 each, respectively;
- 2. For three times the dollar amount proven to have been wrongfully sold to, paid by or withheld from the United States, the States of California, Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, Tennessee,

Texas, Virginia and the District of Columbia, respectively; For maximum civil penalties for all false records, statements, 3. certifications and claims submitted to the United States, the States of California, Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, New Hampshire, Tennessee, Texas, Virginia and the District of Columbia, respectively; For costs of suit and reasonable attorney's fees; and 4. For such other and further relief as the Court deems just and proper. 5. Respectfully Submitted, WARREN * BENSON LAW GROUP Dated: June 5, 2006 Counsel for qui tam plaintiff Thomas Morrow PLAINTIFF DEMANDS A JURY TRIAL Warren • Benson Law Group Dated: June 5, 2006 Counsel for qui tam plaintiff Thomas Morrow

CERTIFICE OF SERVICE

This is to certify that the foregoing Complaint and Notice of Interested Parties has been mailed, postage prepaid, June 6, 2006, to:

Alberto Gonzales, Atty Genl U.S. Department of Justice 10th and Constitution Washington, D.C. 20530 (via certified mail)

Bill Lockyer California Attorney General 1300 I St., Ste. 1740 Sacramento, CA 95814

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Charlie Crist Florida Attorney General The Capitol PL 01 Tallahassee, FL 32399-1050 Debra W. Yang, U.S. Atty. c/o Civil Process Clerk 1200 U.S. Courthouse 312 N. Spring Street Los Angeles, CA 90012 (via certified mail)

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Dated: June 6, 2006

Donald R. Warren